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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,333	09/29/2005	Kenji Motokawa	082368-002100US	2713

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EXAMINER	
HURT, SHARON L	

ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
11/20/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/520,333	MOTOKAWA ET AL.	
	Examiner	Art Unit	
	SHARON HURT	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 July 2008 and 28 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5 and 9-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5 and 9-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 January 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/31/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

The amendments to the claims filed July 31, 2008 and August 28, 2008 have been acknowledged and entered. Claims 1-3, 5 and 9-12 are currently amended.

Status of the Claims

Claims 1-3, 5 and 9-12 are pending and under examination. Claims 4 and 6-8 have been canceled.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a certified English translation of the foreign application must be submitted in reply to this action. 37 CFR 41.154(b) and 41.202(e).

Failure to provide a certified translation may result in no benefit being accorded for the non-English application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 1-3, 5 and 9-12 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement **is withdrawn** pursuant Applicants amendments to the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The rejection of claims 1-3, 5 and 8-12 under 35 U.S.C. 103(a) as being unpatentable over Wasmoen et al. (US Patent 5,770,211) in view of Motokawa et al. (Microbiology and Immunology, 1996, Vol. 40, No. 6, pages 425-433).

The claimed invention is drawn to a vaccine for prophylactic treatment against feline infectious peritonitis (FIPV) infection, wherein said vaccine comprises a polypeptide comprising an amino acid sequence of SEQ ID NO: 1 or SEQ ID NO: 2. The claimed invention is also drawn to a method conferring cellular immunity against feline infectious peritonitis (FIPV), comprising administering the vaccine to a cat.

Wasmoen et al. (hereinafter Wasmoen) teaches a feline infectious peritonitis virus (FIPV) vaccine comprising the N protein of FIPV (column 1, lines 65-67 and column 2, lines 1-4). Wasmoen teaches the vaccine is prepared by creating a recombinant poxvirus containing the N protein of FIPV or immunogenic fragments (column 2, lines 45-48). Wasmoen teaches administering the vaccine to a feline (column 2, lines 5-8).

Motokawa et al. (hereinafter Motokawa) teaches the SEQ ID NO: 1 and SEQ ID NO: 2 from the instant claimed invention (page 428-429, strain KU-2). Motokawa teaches both FIPV types I and II cause infectious peritonitis in cats, however the pathogenicity of type II FIPV is

greater than that of type I FIPV (page 425, 2nd column). Motokawa teaches the prevalence of FIPV type I is higher and about 70% of feline cases are due to type I (page 425, 2nd column).

It would have been *prima facie* obvious to the person of ordinary skill in the art at the time the invention was made to use the N protein in the vaccine formulation as taught by Motokawa in SEQ ID NO: 2. The person of ordinary skill in the art would have been motivated to make a vaccine with the N protein because Wasmoen teaches a FIPV vaccine comprising the N protein is effective and more accessible, and reasonably would have expected success because of the teachings of Wasmoen and Motokawa.

Response to Arguments

Applicant's arguments filed July 31, 2008 have been fully considered but they are not persuasive. Applicants argue "no report on an attempt for developing a vaccine against FIPV using a N-protein of Type 1 FIPV was provided before the present application was filed." This is an obviousness rejection over the combination of references.

Applicants argue "Wasmoen acknowledges ineffectiveness of the N-protein of Type II FIPV as a vaccine against FIPV (col. 1, lines 51-54), and then presents new approach for use of recombinant N and E1 protein of Type II FIPV in a raccoon poxvirus host." Wasmoen teaches the best candidate for a FIPV vaccine would be a vaccine comprising the structural proteins (N protein) of FIPV (col. 1, lines 45-51). Wasmoen also teaches previous attempts were ineffective and a need for an effective vaccine against FIPV using the N protein (col. 1, lines 52-59). Applicants argue "Wasmoen discloses introduction of recombinant N protein with different antigenicity for use as a vaccine from such ineffective N-protein previously known. Wasmoen never teaches the use of N protein of Type I FIPV as a vaccine against FIPV." Wasmoen teaches

a recombinant raccoon virus carrying the N protein of FIPV (Example 1). The instant claims are not exclusive to Type I FIPV and their scope includes an N polypeptide contained within a pox virus. Note that Type I and Type II N proteins can be 93% or more homologous (Motokawa, table 2).

Applicants argue "Motokawa merely discloses the amino acid sequences of an N protein of a Type I FIPV (SEQ ID NO:2), and never teaches use of the N protein as an antigen for a vaccine against FIPV." In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Motokawa teaches motivation to use the N protein of FIPV Type I because Type I is less infectious and more common. A person of ordinary skill in the art would know that the less infectious strain would be a better choice for a vaccine strain and would have greater access to the most common FIPV.

Applicants' argument of unexpected results is not persuasive absent any evidence that one skilled in the art would view cross protection against both types I and II of FIPV to be unexpected. Does the vaccine of Wasmoen not provide cross protection? Are known antigenic regions of type II N protein lacking in type I N protein? Note again that the claims include type II N proteins.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARON HURT whose telephone number is 571-272-3334. The examiner can normally be reached on M-F 8:00 - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharon Hurt

November 12, 2008
/Bruce Campell/
Supervisory Patent Examiner, Art Unit 1648